resource allocation. The objective of this study is to compare the company-predicted budget impact with the actual budget impact of high-cost drugs reimbursed in Ireland. **METHODS:** All drugs submitted to the health service executive (HSE, health care payer in Ireland) for reimbursement under the high-tech drug scheme (a scheme used to administer high cost drugs) from 2009 to 2012 were included in the review. Company estimates of the likely budget impact of the drug in 2013 were extracted from submissions and compared with actual expenditure in 2013 from the health service executive-primary care reimbursement service (HSE-PCRS). Only drugs for which budget impact estimates were available and which were reimbursed by the HSE in 2013 were included in the analysis. **RESULTS:** Ten drugs were included in the analysis, including six cancer drugs, two immunomodulators for multiple sclerosis and rheumatoid arthritis, and two orphan drugs for cystic fibrosis and idiopathic thrombocytopenic purpura. The cumulative expenditure on these drugs in 2013 was €55.8 million compared with a predicted gross budget impact of €53.4 million, representing a €2.4 million underestimate in company submissions. The most significant underestimate related to the drug for multiple sclerosis (€3.4 million) while the biggest overestimate related to the orphan drug for cystic fibrosis (€2.9 million). **CONCLUSIONS:** Company submissions have been shown to both under- and over-estimate budget impact predictions. It is important that budget impact estimates are as realistic as possible in order to effectively inform decisions on resource allocation or reimbursement.

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REDEL STUDY: DIFFERENCES IN REIMBURSEMENT DELAYS IN CEE COUNTRIES

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OBJECTIVES: The dynamic of the reimbursement politics shows a very different pattern in different countries. The REDEL study examined the elapsed time from marketing authorization to the starting date of reimbursement of the original medicines in Central and Eastern European Countries (Austria, Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia). **METHODS:** The basis of comparison were 216 products and their ATC codes selected from the database of the European Medicines Agency which were granted a marketing authorization between 1st January 2007 and 1st July 2013. In the case of these products the research studied the dates, when countries adopted them into their reimbursement system. The adoption was the subject of the study between 1st January 2010 and 1st July 2013. The following three different indicators were calculated in the study: REDEL - the delay between marketing authorization date and reimbursement date; INNREIMB - the number of reimbursed INNs according to a specific country or MAH; SR - Success Rate as the ratio of reimbursed INNs to examined INNs. **RESULTS:** While an average of 403 days elapsed between the authorization and the starting date of reimbursement in Slovenia (mean of 76 products), the same period was 1295 days in Poland (mean of 21 adoptions). The average is 632 days. The top three in the ranking of REDEL of active substances (ATC 1st level – anatomical main group) were dermatologicals (D), respiratory system (R) and Muscolo-skeletal system (M). **CONCLUSIONS:** The results show that even threefold differences exist among the studied countries with regards to the reimbursement delay. An average of almost two years elapse until a producer can have the given product adopted into the reimbursement system in a country (the REDEL steadily increasing in the studied period, while the number of reimbursed products decreasing).

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BLACK BOX AMNOG REBATES: WHAT IS DRIVING THE PRICE IN THE NEGOTIATION WITH THE GKV-SPITZENVERBAND?

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OBJECTIVES: Price negotiations of a pharmaceutical company with the German GKV-Spitzenverband (Association of Statutory Health Insurance) after early benefit assessments can be considered a black box. This analysis aims at providing insights on the parameters that drive the final rebate to predict future pricing decisions and to enhance the negotiation strategy and therefore secure optimal pricing. **METHODS:** Published benefit assessments from the G-BA (Federal Joint Committee) website and the products' prices as listed in the German pharmacy selling system were used as a basis for research. The latter allows a comparison of launch prices (manufacturer selling prices) and prices after the negotiation with the GKV-Spitzenverband (reimbursement prices). The following parameters were analyzed: Rebate size, rebate by added benefit rating, and rebate by therapeutic area. **RESULTS:** By June 2014, 36 products had been through price negotiation, with the rebate of the launch price ranging from 5-71% (average: 25%). The rebate of products with considerable benefit rating ranged from 10-35% (average: 21%). Products with minor added benefit reached rebates between 5-48% averaging at 23%. Products with no quantifiable benefit yielded rebates ranging from 11-44% (average: 24%). Products with no additional benefit had a rebate between 5-71% averaging at 27%. Products in oncology yielded an average rebate of 27%., followed by endocrinology (23%), central nervous system (22%), cardiovascular (21%), and infectious diseases (16%). **CONCLUSIONS:** The better the added benefit rating of a product, the lower is its negotiated rebate. However, only marginal average differences were observed. The rebate per therapeutic area did not reveal obvious patterns: Assessments for oncology products resulted in above average rebates, while rebates for products for infectious diseases were far below the average.

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COMPARISON OF POST-AUTHORISATION MEASURES FROM REGULATORY AUTHORITIES WITH ADDITIONAL EVIDENCE REQUIREMENTS FROM HTA BODIES IN GERMANY

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OBJECTIVES: Regulatory authorities such as the European Medicines Agency (EMA) can make marketing authorisation contingent upon post-authorisation measures (PAMs) so as to fill in information gaps in efficacy and safety. PAMs are generally formulated in agreement with manufacturers, and evaluate clinical hypotheses in an ethical and practical way. In Germany, novel medicines must also undergo an early benefit assessment (EBA) by the Federal Joint Committee (G-BA) following marketing authorisation. G-BA may demand additional evidence in order to formulate an opinion on added therapeutic value, which then leads to determination of reimbursement. We compared selected PAMs with the corresponding G-BA demands to see if they were similar. **METHODS:** Medicines that received a restricted EBA from G-BA before 15 June 2014 were evaluated and compared with their marketing authorisations by EMA. PAMs from EMA, and EBA restrictions from G-BA, were assessed in terms of their required additional evidence. **RESULTS:** Twenty-eight percent of all 79 medicines assessed by G-BA received a restricted EBA. Only nine of those had obligations for PAMs. Four of these were conditional approvals or approval under exceptional circumstances, while five received unconditional marketing authorisation. G-BA justified restricted EBAs for the four conditional approvals based upon agreement with the EMA opinion. For the five unconditional approvals, G-BA required considerably more information than EMA. The additional evidence requested by the two bodies rarely corresponded to one another. EBA restrictions were more influenced by transferability to the German health care context, choice of subgroups and appropriate comparator, than were the corresponding EMA PAMs. **CONCLUSIONS:** G-BA often demands more evidence than specified in EMA PAMs from medicines granted unconditional approval. Although PAMs are discussed and agreed between EMA and manufacturers, G-BA demands and restrictions are not. The possibility for such discussions with G-BA would be an improvement for the future.

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STANDARD COSTS FOR HEALTH ECONOMIC EVALUATIONS: AN INTERNATIONAL COMPARISON

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OBJECTIVES: Country-specific lists of standard costs can reduce the variability of results in health economic evaluations that are attributed to differences in employed data sources and approaches for defining the resource use and unit prices. Moreover they potentially speed up the conduct of health economic evaluations. We aim to investigate which HTA agency officially recognizes and applies a standard cost list and, where such list exists, explore pre-specified procedural and methodological aspects. **METHODS:** Reviewing all national pharmacoeconomic guidelines published on the ISPOR Website http://www.ispor.org/PEguidelines/index.asp in English (i.e., 30 out of 37). Standard cost lists mentioned in the guidelines were, inter alia, compared on the following aspects: i) objective, ii) authorship, iii) release interval, iv) data sources, v) costing perspective, vi) cost categories, and vii) health-state costing. **RESULTS:** Out of the 30 pharmacoeconomic guidelines available in English, a standard cost list was officially recognized and applied by 4 HTA agencies (Canada, England, Australia and the Netherlands). All 4 lists aim to reduce heterogeneity between health economic evaluations in order to increase the comparability. Compiling the standard cost lists was commissioned to external scientific institutions in all 4 countries. Updates of the lists have been published periodically, spanning from anually (e.g. England) to when required for methodological reasons or to ensure currency (e.g. the Netherlands). Data collection was primarily based on claims data and/or official statistics; in the Netherlands, published research and expert opinions can be employed (for estimating resource use). Costs were derived from a payer perspective. Both direct and indirect costs were stated, except for Australia (only direct costs). No country presented costs in relation to health states. **CONCLUSIONS:** Standard cost lists are mentioned in 13% of the pharmacoeconomic guidelines available in English. The 4 lists conicide on many procedural and methodological aspects. Heterogeneity arises mainly from country-specific costs.

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REGULATORY APPROVAL TO PATIENT ACCESS, AN EVALUATION OF EU5 AND US NATIONAL TIMING DIFFERENCES: AN UPDATE

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OBJECTIVES: Examine the time between regulatory approval and launch/pricing and reimbursement (P&R) approval in the US and EU5 countries. **METHODS:** Examined new molecular entities, formulations and combinations with EMA approval between Jan 2009 and May 2014. Additional analysis of products launched between April 2013 and May 2014. Time comparison for general medicines vs. orphan/oncology indications was made including shifts over time. Data gathered from: USA: FDA approval date, wholesale; acquisition cost effective date; UK/Germany: Product availability/introduction; France: P&R decision (Agrément collectivités/date published in Journal Officiel); Italy: First Official Gazette P&R Decree publication; and Spain: Date of commercialization. **RESULTS:** Overall, for launches between Jan 2009 and May 2014, the average time from FDA approval to US launch was 6 weeks (oncology 4 weeks; orphan drugs 2 weeks). Across the EU5, Germany remains the fastest to market. Analysis of new products launched between April 2013 and May 2014 shows time to access in Spain has increased vs. the previous 5 years (75 vs. 54 weeks). Limited numbers of orphan drugs have completed full Spanish P&R process with 106 weeks to launch far exceeding all drugs (75 weeks). Italian average time to complete P&R is 69 weeks, while average time to be listed in class C-nn, without national reimbursement, is only 18 weeks. UK average time to oncology launch appears short (16 vs. 20 weeks), however HTA assessments often mean significant access delays. French orphan drugs assessment is faster vs. all drugs (46 vs. 50 weeks). **CONCLUSIONS:** The time to P&R post-regulatory approval increased ~3 weeks in Italy and ~21 weeks in Spain for products launched in the latest year vs. all drugs with EMA approvals between Jan 2009 and Dec 2013.